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December 22, 2020

VIA E-MAIL

Adam M. Slater, Esquire
Mazie Slater Katz & Freeman, LLC
103 Eisenhower Parkway
Roseland, NJ 07068

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation, No. 1:19-md-2875: Designation of Federal Rule of Civil Procedure 30(b)(6) Witnesses

Dear Counsel:

As a follow-up to our call last week during which we disclosed the general topics on which our clients' witnesses would testify pursuant to Federal Rule of Civil Procedure 30(b)(6), and pursuant to the Court's order (ECF Doc. No 664), enclosed please find the Rule 30(b)(6) witness designations for Zhejiang Huahai Pharmaceutical Co., Ltd., Solco Healthcare U.S., LLC, Prinston Pharmaceutical Inc., and Huahai U.S., Inc. We have previously disclosed the location of each witness to you by email dated December 9, 2020, and proposed dates for each witness by email dated December 17, 2020.

Very truly yours,

Jessica Priselac

Jessica Priselac

JP
Encl.

Zhejiang Huahai Pharmaceutical Co., Ltd – 30(b)(6) Witnesses		
Testing of Valsartan API		
No.	**Topic**	**Corporate Designee(s)**
1	1. The cause of the contamination of ZHP's valsartan API with nitrosamines including NDMA.	Min Li
2	2. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the ZHP API.	Min Li Jucai Ge
3	3. The testing performed by ZHP or its agents, to evaluate the purity and contents of ZHP's API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.	Qiangming Li
4	4. The testing performed by ZHP or its agents, to evaluate the purity and contents of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.	Minli Zhang
5	5. The testing performed by any entity or person other than ZHP or its agents but known to ZHP, to evaluate the purity and contents of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.	Qiangming Li
6	6. The testing performed by any entity or person other than ZHP or its agents but known to ZHP, to evaluate the purity and contents of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.	Minli Zhang
7	7. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.	Qiangming Li Min Li
8	8. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.	Minli Zhang

Zhejiang Huahai Pharmaceutical Co., Ltd – 30(b)(6) Witnesses		
9	9. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.	Qiangming Li
10	10. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.	Minli Zhang
11	11. ZHP's evaluation of the potential risks to the purity or contents of ZHP's valsartan API posed or caused by solvents used during the manufacturing process (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.	Peng Dong
12	12. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of the solvents utilized in the manufacture of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.	Qiangming Li
13	13. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of the solvents utilized in the manufacture of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.	Minli Zhang
14	14. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of the solvents utilized in the manufacture of ZHP's API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.	Qiangming Li
15	15. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of the solvents utilized in the manufacture of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that	Minli Zhang

Zhejiang Huahai Pharmaceutical Co., Ltd – 30(b)(6) Witnesses		
	manufactured ZHP's finished dose for sale in the United States.	
16	16. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of the production equipment utilized in the manufacture of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.	Qiangming Li
17	17. The chromatogram and mass spectrometry results for all testing by ZHP or its agents of the production equipment utilized in the manufacture of ZHP's valsartan finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.	Minli Zhang
18	18. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of the production equipment utilized in the manufacture of ZHP's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured ZHP's valsartan API for sale in the United States.	Qiangming Li
19	19. The chromatogram and mass spectrometry results for all testing by any entity or person other than ZHP or its agents but known to ZHP, of the production equipment utilized in the manufacture of ZHP's finished dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.	Minli Zhang
20	20. The extent of the actual and potential nitrosamine contamination of ZHP's valsartan API and finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.	Qiangming Li, API Minli Zhang, finished dose
Quality Assurance and Quality Control Activities		
No.	**Topic**	**Corporate Designee(s)**
21	21. ZHP's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of ZHP's valsartan API (regardless of intended sale location) in any	Jucai Ge

Zhejiang Huahai Pharmaceutical Co., Ltd – 30(b)(6) Witnesses		
	facility that manufactured ZHP's valsartan API for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)	
22	22. ZHP's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of ZHP's valsartan finished dose (regardless of intended sale location) in any facility that manufactured ZHP's finished dose for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)	Minli Zhang
23	23. ZHP's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of ZHP's valsartan API (regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States. (The parties to meet and confer to identify the relevant cGMP's.)	Jucai Ge
24	24. ZHP's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of ZHP's finished dose (regardless of intended sale location) in any facility that manufactured ZHP's finished dose for sale in the United States. (The parties to meet and confer to identify the relevant cGMP's.)	Minli Zhang
25	25. The "relevant SOP's, QS, testing method, validation reports, equipment calibration records, preventive maintenance plan and change control records, etc." referenced at b.6. on ZHP00004355.	Jucai Ge
26	26. The distinction between technical inquiries and deviation reports, as those terms are defined in ZHP's documents and in the ordinary course of business.	Jucai Ge, API Minli Zhang, Finished Dose

Zhejiang Huahai Pharmaceutical Co., Ltd – 30(b)(6) Witnesses		
27	27. The processes and procedures for handling technical inquiries.	Jucai Ge, API Minli Zhang, Finished Dose
28	28. The processes and procedures for handling deviation reports.	Jucai Ge, API Minli Zhang, Finished Dose
29	29. The technical inquiries received by ZHP relating to ZHP's valsartan API, (regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States.	Jucai Ge
30	30. The technical inquiries received by ZHP relating to ZHP's valsartan Finished Dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.	Minli Zhang
31	31. The deviation reports drafted by or received by ZHP relating to ZHP's valsartan API (regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States.	Jucai Ge
32	32. The deviation reports drafted by or received by ZHP relating to ZHP's valsartan Finished Dose (regardless of intended sale location) manufactured in any facility that manufactured ZHP's finished dose for sale in the United States.	Minli Zhang
Process Development		
No.	**Topic**	**Corporate Designee(s)**
33	33. The "primary process validation of Process II (Zn cl2) completed in April 2012" referenced on ZHP00004372.	Peng Dong
34	34. The modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API, including: (1) the reasons for the modifications, (2) the testing and evaluation in connection with the modification, and (3) the relationship between the modifications and the nitrosamine contamination of ZHP's valsartan API (regardless of intended sale location) in any	Peng Dong

Zhejiang Huahai Pharmaceutical Co., Ltd – 30(b)(6) Witnesses		
	facility that manufactured ZHP's valsartan API for sale in the United States.	
35	35. Any evaluation conducted by or on behalf of ZHP with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API (regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States.	Peng Dong Eric Gu
35A	35A. ZHP's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for ZHP's valsartan API (regardless of intended sale location) in any facility that manufactured ZHP's valsartan API for sale in the United States.	Eric Gu
36	36. ZHP's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of ZHP's valsartan API, and ZHP's valsartan finished dose.	Min Li
37	37. The process changes referenced in section 3.4.1 on ZHP00004371.	Peng Dong
Communications with Regulatory Agencies		
No.	**Topic**	**Corporate Designee(s)**
38	38. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API.	Linda Lin
39	39. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's finished dose.	Linda Lin
40	40. ZHP's disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of ZHP's valsartan API with nitrosamines including NDMA and NDEA.	Linda Lin
41	41. ZHP's filings with regulatory authorities, including the FDA, regarding manufacturing process changes for ZHP's Valsartan API Drug Master Filings.	Linda Lin

Zhejiang Huahai Pharmaceutical Co., Ltd – 30(b)(6) Witnesses		
ZHP's Communications with API and Finished Dose Customers and Downstream Customers		
No.	**Topic**	**Corporate Designee(s)**
42	42. ZHP's oral and written communications with Novartis with regard to the content/purity/contamination of ZHP's valsartan API.	Jie Wang
43	43. ZHP's oral and written communications with ZHP's valsartan API Customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the ZHP valsartan API.	Jie Wang
44	44. ZHP's oral and written communications with ZHP's valsartan finished dose customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the ZHP valsartan finished dose.	Hai Wang Minli Zhang
45	45. ZHP's oral and written statements (defined to include representations and warranties) to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of ZHP's valsartan API or ZHP's valsartan finished dose.	Minli Zhang
46	46. ZHP's product recall for ZHP's valsartan API or ZHP's valsartan finished dose, including who ZHP communicated with, how, about what, and the retention of recalled or sequestered ZHP valsartan API or ZHP valsartan finished dose.	Jucai Ge, API Minli Zhang, Finished Dose
47	47. All credits, indemnification, refunds, and/or penalties paid or provided by or to ZHP in connection with the nitrosamine contamination of ZHP's valsartan API and ZHP's valsartan finished dose.	Jie Wang, API Hai Wang, Finished Dose
Compliance with cGMPs		
No.	**Topic**	**Corporate Designee(s)**
48	48. ZHP's compliance or non-compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, as it relates to the manufacture, quality assurance, quality control, and sale of ZHP's API and ZHP's valsartan finished dose (regardless of intended sale location) manufactured in	Jucai Ge, API Minli Zhang, Finished Dose

Zhejiang Huahai Pharmaceutical Co., Ltd – 30(b)(6) Witnesses		
	any facility that manufactured ZHP's valsartan API and ZHP's valsartan finished dose for sale in the United States.	
49	49. The "GMP and process training" referenced in the Personnel section on ZHP00004368.	Jucai Ge
Product Tracing		
No.	**Topic**	**Corporate Designee(s)**
50	50. Tracing of batches and lots of ZHP's valsartan API sold downstream and ultimately intended for use by consumers in the United States.	Jie Wang
51	51. Tracing of batches and lots of ZHP's valsartan finished dose sold downstream and ultimately intended for use by consumers in the United States.	Hai Wang
52	52. The pricing of ZHP's valsartan API that as ultimately sold in the United States.	Jie Wang
53	53. The pricing of ZHP's valsartan finished dose that was ultimately sold in the United States.	Hai Wang
54	54. The gross and net profits to ZHP from the sale of ZHP's valsartan API in the United States.	Jie Wang
55	55. The gross and net profits to ZHP from the sale of ZHP's valsartan finished dose in the United States.	Hai Wang
56	56. The quantity/units of ZHP's valsartan API sold in the United States.	Jie Wang
57	57. The quantity/units of ZHP's valsartan finished dose sold in the United States.	Hai Wang
58	58. The ZHP valsartan API sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days in advance of deposition during the meet and confer process).	Jie Wang
59	59. The ZHP valsartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days in advance of deposition during the meet and confer process).	Hai Wang

Prinston Pharmaceutical Inc. – 30(b)(6) Witnesses		
Process Development		
No.	**Topic**	**Corporate Designee**
1	36. ZHP's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of ZHP's valsartan API, and ZHP's valsartan finished dose.	Lijie Wang
Communications with Regulatory Agencies		
No.	**Topic**	**Corporate Designee**
2	38. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API.	Lijie Wang
3	39. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's finished dose.	Lijie Wang
4	40. Disclosures by or on behalf of ZHP, Huahai US, Inc., Solco, and/or Prinston to regulatory authorities including the FDA, with regard to the actual or potential contamination of ZHP's valsartan API with nitrosamines including NDMA and NDEA.	Lijie Wang
Communications with API and Finished Dose Customers and Downstream Customers		
No.	**Topic**	**Corporate Designee**
5	44. Oral and written communications by or on behalf of ZHP, Huahai US, Inc., Solco, and/or Prinston with their valsartan finished dose customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the ZHP valsartan finished dose.	Hai Wang
6	46. ZHP's product recall for ZHP's valsartan API or ZHP's valsartan finished dose, including who ZHP, Huahai US, Inc., Solco, and/or Prinston communicated with, how, about what, and the retention of recalled or sequestered ZHP valsartan API or ZHP valsartan finished dose.	Hai Wang

Solco Healthcare U.S. – 30(b)(6) Witnesses		
Testing of Valsartan API		
No.	**Topic**	**Corporate Designee**
1	20. The extent of the actual and potential nitrosamine contamination of ZHP's valsartan API and finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.	Hai Wang
Communications with API and Finished Dose Customers and Downstream Customers		
No.	**Topic**	**Corporate Designee**
2	44. Oral and written communications by or on behalf of ZHP, Huahai US, Inc., Solco, and/or Prinston with their valsartan finished dose customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the ZHP valsartan finished dose.	Hai Wang
3	45. Oral and written statements (defined to include representations and warranties) by or on behalf of ZHP, Huahai US, Inc., Solco, and/or Prinston to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of ZHP's valsartan API or ZHP's valsartan finished dose.	Hai Wang
4	46. ZHP's product recall for ZHP's valsartan API or ZHP's valsartan finished dose, including who ZHP, Huahai US, Inc., Solco, and/or Prinston communicated with, how, about what, and the retention of recalled or sequestered ZHP valsartan API or ZHP valsartan finished dose.	Hai Wang
5	47. All credits, indemnification, refunds, and/or penalties paid or provided by or to ZHP, Huahai US, Inc., Solco, and/or Prinston in connection with the nitrosamine contamination of ZHP's valsartan API and ZHP's valsartan finished dose.	Hai Wang
Product Tracing		
No.	**Topic**	**Corporate Designee**
6	51. Tracing of batches and lots of ZHP's valsartan finished dose sold downstream and ultimately intended for use by consumers in the United States.	Hai Wang
7	53. The pricing of ZHP's valsartan finished dose that was ultimately sold in the United States.	Hai Wang

Solco Healthcare U.S. – 30(b)(6) Witnesses		
8	55. The gross and net profits to ZHP, Huahai US, Inc., Solco, and/or Prinston from the sale of ZHP's valsartan finished dose in the United States.	Hai Wang
9	57. The quantity/units of ZHP's valsartan finished dose sold in the United States.	Hai Wang
10	59. The ZHP valsartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days ahead of deposition during meet and confer process).	Hai Wang

Huahai U.S., Inc. – 30(b)(6) Witness		
Communications with Regulatory Agencies		
No.	**Topic**	**Corporate Designee**
1	38. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API.	Lijie Wang
2	40. Disclosures by Huahai or by Huahai on behalf of ZHP, Solco, and/or Prinston to regulatory authorities, including the FDA, with regard to the actual or potential contamination of ZHP's valsartan API with nitrosamines including NDMA and/or NDEA.	Lijie Wang
3	41. ZHP's filings by Huahai or by Huahai on behalf of ZHP, Solco, and/or Prinston with regulatory authorities, including the FDA, regarding manufacturing process changes for ZHP's Valsartan API Drug Master Filings.	Lijie Wang